Fair Use: A Workable Concept in European Patent Law?

Geertrui Van Overwalle

Contents

Abstract Over the last decade, the patent system has sparked significant controversy worldwide. Concerns have been expressed about the expansion of the patent system, both in terms of patentable subject matter and of the numbers of patents granted. Irritation has equally been voiced with regard to certain (inadequate or unfair) uses of the patent system. As to the latter, various remedies have been put forward to deal with inadequate licensing practices (Sect. 2). However, patent law's toolbox may not be sufficient to redress restrictive licensing behaviour in all its facets. Recalling to mind the rationale of patent law and the underlying 'social contract' (Sect. 3), an alternative and seemingly more flexible remedy to deal with unreasonable behaviour is examined: the fair use exception (Sect. 4). We explore whether the fair use exception from US copyright law may be implemented in European patent law, and provide a tool to extend the 'social contract' to the post-grant phase. We field test the fair use doctrine in Europe by applying the doctrine on the Myriad case, a prime example of problematic licensing in the field of human genetics (Sect. 5). The fair use approach may equally be tested in other

G. Van Overwalle is Professor of IP Law at the University of Leuven.

G. Van Overwalle
Centre for Intellectual Property Rights, University of Leuven, Leuven, Belgium
e-mail: Geertrui.VanOverwalle@law.kuleuven.be

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technological areas, such as the ICT or telecom sector, in order to learn to what extent the concept can apply to all fields of technology (Sect. 6).

1 Introduction

In the past decade, the patent system has been seriously criticised. For quite some time, academics have been rather critical about the patent system.[1] Nowadays, also newspapers comment on patent cases and often portray patents as a negative story.[2] A first trend that has received a lot of criticism relates to the unbridled *expansion* of the patent system, both in terms of patentable subject matter and the number of patents granted.[3] The scope of patentable subject matter has been stretched considerably to adapt patent law to the new realities of ICT and genetics by extending protection to computer-related inventions and biological material. Concerns are raised about the potentially harmful effect of such expansion on the freedom to operate and on follow-on innovation. Patent law has expanded not only in respect to scope but even more so in respect to the number of patents granted.[4] Recent years have seen a remarkable increase in patents in the fields of ICT technology and biotechnology.[5] Concerns have been voiced about the impact of the current patent surge on the quality of patents and the fluent exchange of ICT and genome-related technology in a landscape of patent thickets. At present, technological areas such as ICT technology and biotechnology are so crowded with patents that the freedom to use protected inventions may be considerably limited.

A second trend that has become visible over the last few years is the growing sensitivity to unreasonable *behaviour* of patent rights holders.[6] In recent years, some companies have either refused to license some inventions or have licensed them exclusively at relatively high prices. The current *Zeitgeist* seems to be more

[1] There is a wide array of US scholarly literature expressing discontent with the current patent system. See Bessen and Meurer (2008), Boldrin and Levine (2008), Burk and Lemley (2009), and Jaffe and Lerner (2004). The author of the present paper also looked into the shortcomings of the patent system from an international perspective; see Van Overwalle and van Zimmeren (2009), pp. 415–442.

[2] For an example in the genetics area, see Caulfield et al. (2007), pp. 850–855.

[3] See Van Overwalle and van Zimmeren (2009), and the references cited there.

[4] Patent filings worldwide grew by 7.2 % in 2010, after having fallen by 3.6 % in 2009. That growth was driven by a steep filing increase in China and the US, which accounted for four-fifths of worldwide growth. An all-time high of 1.98 million applications were filed globally, consisting of 1.23 million resident applications and 0.75 million non-resident applications. See World Intellectual Property Indicators (2011).

[5] For some details in genetics, see Hopkins et al. (2007), p. 185; Jensen and Murray (2005), p. 239. For some details in other sectors, see Sheehan et al. (2003).

[6] See Van Overwalle and van Zimmeren (2009), and the references cited there.

sensitive to such uses of the patent system. One saga that made the headlines worldwide is the Myriad case, a case in the field of genetics where restrictive licensing policies have been widely applied. Myriad, a US company owning a suite of US and European patents covering breast and ovarian cancer (BRCA) genes,[7] demanded fees of $2,400[8] or more for carrying out its own test at a few licensed centres and tried to stop all other tests involving the BRCA genes in public health genetic laboratories. It was this behaviour, rather than the patents themselves, that led to wide controversy. At first sight, other sectors such as ICT and telecom may seem to be less prone to restrictive licensing behaviour. Due to the nature of the products, and to the importance of interoperability and compatibility, there is a recurrent need among companies to (cross-)license their patents. However, when dealing with standard essential patents, companies such as Apple and Samsung endlessly debate on the exact scope and level of FRAND (fair, reasonable, and non-discriminatory) licensing terms. Concerns are being expressed on how time-consuming negotiations and restrictive and/or unreasonable licensing practices can frustrate access to technology and opportunities for further research and development.

In summary, the growing discontent with patent law manifests itself in relation to patentable subject matter and the coming into *existence* of patent rights. Recent events illustrate that the irritation is also orientated towards the *exercise* of patent rights. Our chapter deals with the growing unease with regard to the exercise of patent rights, in particular with restrictive and/or unreasonable licensing behaviour. We kick off by looking at the various remedies in current patent law to deal with such behaviour.

2 Patent Law's Toolbox

A first instrument to limit the rights of restrictive patentees is the *research exception*.[9] Although the European-style research exception may provide protection against infringement for many (university or private sector) scientists involved in

[7] See Matthijs et al. (2013), pp. 704–710; Huys et al. (2012), pp. 441–448; Huys et al. (2011), pp. 1104–1107.

[8] Matthijs and Hodgson (2008), pp. 58–60; Matthijs (2007), pp. 27–44.

[9] In Europe, a list of limitations to the right of a patentee was suggested for the first time in the Community Patent Convention (CPC) of December 15, 1975, and reintroduced as Article 9 of the Proposal for a Council Regulation on the Community Patent of August 1, 2000. In the meantime, the Unitary Patent Package (UPP) saw the light and formally adopted the research exception in Article 27 (b) of the Agreement on a Unified Patent Court, Brussels, January 11, 2013 ("The rights conferred by a patent shall not extend to any of the following: acts done for experimental purposes relating to the subject matter of the patented invention"). Anticipating the implementation of the CPC, the 'mother' provision on the research exception was introduced in many EPO member states.

basic research,[10] it is doubtful whether it can constitute a safe harbour for researchers concentrating on applied research with a commercial finality. As a possible remedy against restrictive licence behaviour, critical analyses have also been prepared on the *compulsory licence* mechanism in patent law. In most countries, a government or a court can usually compel a patent holder to license his rights for reasons of dependency or insufficient exploitation. Recently, compulsory licences have been provided to address the potential hindering effects of patents in public health care.[11,12] One might argue that there is yet another instrument in patent law, namely *patent term duration*. However, the patent term duration defence is too limited to deal with the problems discussed here.

Measures have also been contemplated outside patent law, more particularly in competition law. Even though European competition law leaves considerable freedom to the patentees to set up their licensing agreements and does not prohibit exclusive licensing as such, a measure is available to deal with cases of extreme monopolistic licensing behaviour of patent holders: the *abuse of dominant position*.[13]

The line of research on restrictive licensing behaviour has taught, however, that those instruments, either internal or external to patent law, may well not be sufficient to meet the growing concern regarding the hindering effects of patents. Alternative and more flexible remedies to redress unreasonable patent rights behaviour may be necessary. One idea that struck our attention and whetted our curiosity is implementing the fair use exception from copyright into the patent law arena.

3 The Social Contract

To appreciate the plea for an introduction of a fair use concept in patent law, it is necessary to dig into patent law legitimation theories and the patent law rationale.[14] The debate on the legitimation of the patent system has a long and turbulent history

[10] See van Zimmeren and Van Overwalle (2014).

[11] In France, Switzerland, and Belgium, such a compulsory licence 'for public health' has been introduced. For more, see van Zimmeren and Van Overwalle (2011).

[12] Compulsory licences for European patents are regulated by national law. Compulsory licences for European patents with unitary effect are governed by the laws of the participating Member States as regards their respective territories (see Recital 10 Regulation (EU) 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, *Official Journal of the European Union*, L 361/1, 31 December 2012).

[13] Article 102 Treaty on the Functioning of the European Union (TFEU), *Official Journal of the European Union*, C 83/47, March 30, 2010. For more details, see van Zimmeren (2011).

[14] This section mainly reiterates some of the thoughts I have expressed in Van Overwalle (2007); Van Overwalle and van Zimmeren (2009). Under the heading 'Signs of the Times: Evolving Reasons for Patent Fair Use' Katherine Strandburg provides additional, interesting rationales for the introduction of a fair use exception in patent law (see Strandburg 2011, at pp. 281–289).

in both academic and political circles. The present consequentialist justification, focusing on both the 'incentive to invent and innovate' and on the 'incentive to disclose' argument,[15] is probably most accepted to date, as it reconciles both the private and public interests. The private interest of the inventor is served through the grant of a limited exclusionary right as an incentive to further creativity and inventiveness (including necessary investments in research and development). The public interest benefits through the development of accessible goods and services and the dissemination of technical knowledge, thanks to the disclosure requirement. The TRIPS Agreement equally reflects this utilitarian approach, balancing two objectives: rewarding compensation for creators and inventors for innovation, on one hand, and promoting the interests of the public at large in securing access to science and technology, on the other hand. Articles 7,[16] 8,[17] and 30[18] of the TRIPS Agreement confirm this effort for achieving an equilibrium,[19] in other words, a "social contract".[20] A patent right cannot be viewed as a title giving (almost) complete freedom of action but rather as temporary permit to exploit monopoly rights under fair and reasonable conditions, in other words, as a duty-bearing privilege.[21] In the light of the many controversies surrounding gene and disease

[15] For more on this theory, as well as the other justifications theories, see Burk and Lemley (2009); Drahos (1996); Machlup (1959); Penrose (1951); Sterckx (2005); Van Overwalle and van Zimmeren (2009).

[16] Article 7 stipulates that "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

[17] Article 8 equally stipulates that "(1) Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. (2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology".

[18] Article 30 sets forth that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". According to the drafters of the *Copyright Declaration—A Balanced Interpretation of the "Three-Step Test" in Copyright Law* (available at http://www.ip.mpg.de/de/pub/aktuelles/declaration-threesteptest.cfm, last visited June 18, 2013), the fact that third party interests are not explicitly mentioned in the three-step test as applied in copyright law does not detract from the necessity of taking such interests into account. Rather, it indicates an omission that must be addressed by the judiciary.

[19] Similarly Gervais (2003), p. 81, point 2.10.

[20] The term "social contract" is used by Lord Hoffman in the House of Lords' Decision of 21 October 2004 (*Kirin-Amgen and others v. Hoechst Marion Roussel and others*) [2004] *UKHL* 46, § 77; the term "implicit social contract" is set forth by Baldwin (2007).

[21] "If the purpose in creating the privilege is to fulfil some approved goal then it should also follow that the privilege [patent] holder is subject to duties not to exercise the privilege in a way that defeats the purpose for which the privilege [patent] was granted", Drahos (1996), at p. 220. Similarly,

patents and the growing discontent with some undesirable effects and undesired excrescences of the current patent system, there is an urgent need to re-explore this concept.

The social contract underlying the patent system is embedded in patent rules that are being put to the test day by day at the event of the *grant*, the coming into *existence* of patent rights. In view of the many concerns with regard to the potential hindering effects of the restrictive licensing behaviour of patent holders in genetics, the social contract test should be extended to the *post-grant* level and should also be challenged with regard to the *exercise* of patent rights.

At present, patent holders have wide discretion on how to exercise their rights, and European patent law hardly provides rules with regard to exploitation and licensing. Such tools, either internal or external to patent law, should definitely be used to meet the growing concern regarding the hindering effects of patents. However, does that suffice? Are a number of exceptions and a mechanism aimed at limiting cases of *extreme* restrictive licensing behaviour sufficient to balance private and public interests with regard to the exercise of rights? Does the social contract not require that *all un*reasonable or *un*fair licensing behaviour detrimental to public health be forbidden? In genetics, it was not the grant of the BRCA patents as such that led to a worldwide commotion but rather the exorbitant fees and the refusal to license to public genetic labs that aroused emotions. From a pure competition law perspective, it is questionable whether the Myriad business model would infringe competition law and could be qualified as an abuse of dominant position. From a wider perspective, however, one could argue that the Myriad licensing behaviour is a threat to the social contract embedded in patent law and should therefore be forbidden.

Further concrete efforts from the legislator to design institutional and legal responses to monitor the exercise of patent rights in an attempt to safeguard an adequate balance between private and public interests in the *post-grant* phase might be considered. And that is where the fair use exception might step in.

4 Fair Use

Studying the plasticity of the fair use concept is not totally new. In a pioneering article, Maureen O'Rourke already examined the introduction of a doctrine of fair use in patent law.[22] O'Rourke argues that patent law should adopt a fair use doctrine. The fair use concept eases some of the tensions created by strong patent rights and may play a valuable role in balancing exclusive rights and public welfare.

"Holders of intellectual property privileges are subject to those duties that maximize the probability that the purpose for which the privilege was first created is achieved" (Drahos 1996, at p. 221); "The grant of these monopolies would be tied to the idea of duty. Duty-bearing privileges would form the heart of an instrumentalism of intellectual property" (Drahos 1996, at p. 223).

[22] O'Rourke (2000).

Building on the work of O'Rourke, Katherine Strandburg equally takes the view that a fair use type infringement exception should take its place in patent law's toolbox.[23] A fair use exception can carve out specific types of uses, using a scalpel rather than a cleaver to shape a socially beneficial patent scope.[24] Infringement exceptions can account for the fact that different uses of patented technology have different social costs and benefits.[25]

The efforts of O'Rourke and Strandburg, as well as writings from other scholars such as De Larena,[26] have mainly focused on the particular US context. The present analysis aims at widening the conversation and theorising on the implementation of the US fair use copyright concept in European patent law. On the other hand, the present article is more limited in scope and far more modest than previous scholarly writings on this topic. Different from the aim of O'Rourke and Strandburg to establish a fully fletched doctrine of fair use in patent law and to contemplate *new* factors,[27] the current chapter mainly aspires to test to what extent the prevailing copyright fair use theory and the *incorporated* four factors can be operationalised. The underlying question is whether fair use can provide relief for some of the (alleged) harmful consequences of patent rights. The present chapter looks at the Myriad case, a prime example of a problematic patent case in the field of human genetics, to field test the fair use doctrine in Europe.[28] Further research could elaborate on this approach and complement this first assessment by putting restrictive and/or unreasonable licensing cases in other technological areas, such as ICT or telecom, to test.

Let us now turn to the origin of fair use, more particularly US copyright law. Copyright law (US) and *droit d'auteur* (Europe) fundamentally differ in their conceptual approach on the protection of creations of the mind.[29] The main

[23] Strandburg (2011).

[24] Strandburg (2011), at p. 277.

[25] Strandburg (2011), at p. 277.

[26] De Larena (2005).

[27] Strandburg (2011).

[28] Even though the Myriad saga may well have come to a standstill on June 13, 2013, in the US with the decision of the Supreme Court, the current legal framework in Europe remains quite cumbersome, as European and national patent legislation and case law widely allow patenting of isolated genomic DNA and complementary DNA (c-DNA). See article 5 of Directive 98/44/EC of 6 July 1998 of the European Parliament and of the Council on the legal protection of biotechnological inventions (*Official Journal L* 213, 30/07/1998 p. 0013) and the legislation in the various EU Member States, having copied (more or less) article 5. Article 5 sets forth that the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, *cannot* constitute patentable inventions (par. 1) and that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, *may* constitute a patentable invention, *even if the structure of that element is identical to that of a natural element* (par. 2—my Italics). Par. 3 adds that the industrial application [read: function] of a sequence or a partial sequence of a gene must be disclosed in the patent application.

[29] See Strowel (1993).

difference between the two regimes relates to the very nature of the granted rights. US copyright law looks at the rights of authors as mainly economic rights, the author being seen as a provider of a product. In contrast, European *droit d' auteur* is rather based on natural law theory and focuses on the non-patrimonial dimension of the author's creation. Notwithstanding the different approaches, both copyright law and *droit d'auteur* grant an exclusive right to the author to reproduce or authorise the reproduction of her/his work, in any manner and form she/he wishes, be it direct or indirect, temporary or permanent, in part or in whole.

Equally, both regimes have developed exceptions to the main right(s) in an attempt to safeguard the balance between public and private interests. However, the US and Europe substantially differ in the way the exceptions have been conceptualised. The US has introduced a flexible, open regime through the development of a doctrine of fair use, whereas Europe has established a rather rigid, closed regime through the implementation of a limited list of exceptions.

The US doctrine of fair use is a statutory codification of a hundred years of judicial decisions, excusing certain "salutary" uses from infringement liability meeting certain assessment criteria.[30] Article 107 of the Copyright Act provides that certain uses are fair and non-infringing depending on a calculus of four factors.[31] Article 107 stipulates:

> Notwithstanding the provisions of sections 17 U.S.C. § 106 and 17 U.S.C. § 106A, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include:
> 1. the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
> 2. the nature of the copyrighted work;
> 3. the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
> 4. the effect of the use upon the potential market for or value of the copyrighted work.

In European *droit d'auteur*, the concept of fair use is not present as such. Unlike US copyright law and their open approach, European copyright law permits only a limited list of exceptions[32] and does not have the open-ended authority to resolve

[30] Goldstein (2001), at p. 293.

[31] Goldstein (2001), at p. 293. Some scholars have argued that there is a fifth factor at play: "Empirically, it can be demonstrated that judges also invoke other factors, especially a hidden fifth factor—namely, the extent to which the claimed fair use serves the public interest—without which few, if any, major federal appellate decisions affirming fair use are likely to be found"; see Reichman and Okediji (2012). Examining whether a fifth factor is really at play, and to what extent the notion of "public policy" differs from the concept of "public interest" is very important, but goes beyond the scope of the current paper. See Van Overwalle (2000).

[32] Guibault (2002); Hugenholtz and Okediji (2008).

cases outside the specifically listed categories.[33] The list is laid down in Directive 2001/29 on Copyright and Related Rights in the Information Society,[34] more in particular in article 5. The exceptions listed in article 5 (1) are mandatory, whereas the exceptions laid down in article 5 (2) and (3) are optional.

Consequently, European Member States had to remove exceptions that did not appear in article 5 (2) and (3) and amend exceptions that conflicted with them.[35] Moreover, Member States were not allowed to enact exceptions outside the list provided in article 5 (2) and (3). However, they could keep "traditional" exceptions of lesser importance as long as they only concerned analogue uses.

Thoughtful observers set forth that the strength of the US fair use doctrine is the considerable flexibility it provides in balancing the interests of copyright owners, subsequent authors, and the public. Fair use, however, is often unfavourably judged for its unpredictability and case-by-case nature.[36] Comparing the US open list approach with the European closed list approach leads experts to believe that an advantage of the closed list over fair use is that a list of exceptions is more specific and predictable, whereas an advantage of fair use over an exceptions list is that an open list is more flexible and adaptable over time.[37]

5 Fair Use and European Patent Law

Can the fair use doctrine be implemented in European patent law? The legal basis to introduce a fair use test in patent law might be found in the TRIPS Agreement, in particular in Article 30, stating that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". Article 30 is considered to legitimise the closed list exceptions in current European patent law. Is there a good reason why the same Article 30 could not be employed to introduce new hypotheses to the closed list or—more radically—to switch to an open list and apply the US fair use factors as parameters to assess whether certain uses could be exempted from patent infringement?

[33] Goldstein and Hugenholtz (2010), at p. 364. Cf. Goldstein (2001), at p. 293.

[34] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the Harmonization of Certain Aspects of Copyright and Related Rights in the Information Society, *OJ. L* 167, 22/06/2001 pp. 10–19 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0029:en:NOT, last visited September 24, 2013).

[35] See Hart (1998), at p. 169.

[36] Samuelson (2008–2009), at pp. 2540–2541 and the authors cited there.

[37] Samuelson (2008–2009), at pp. 2540–2541 footnote 17.

On the other hand, one could easily think of various objections against the introduction of a fair use concept in European patent law. Foremost, there is wide disagreement in academic scholarship about the feasibility of 'legal transplants'. The same legal rule will operate quite differently in different countries, with differing traditions.[38] Furthermore, the argument has been raised that the fair use doctrine can only be invoked as a 'defense' on the side of the alleged infringer and cannot prescribe the behaviour of the patent holder. Last but not least, litigation costs are likely to be very expensive.[39]

Let us, for a moment, put the pros and cons of transplanting a known legal concept to a new legal environment aside and limit ourselves to testing the fair use concept in a prime case of restrictive licensing behaviour, namely the Myriad case, and evaluate to what extent the four conditions are fulfilled in this setting.

(1) The purpose and character of the use

In order for the fair use exception to apply and in line with US copyright law, the *intent of the alleged infringer* should be taken into account, on a case-by-case basis. It seems to be generally accepted that the use, in order to be exempted, has to lie between two extremes. The first extreme is the case where a third user employs the patented product or method to sell his/her own products on the market, which does not appear to be fair at all. The second extreme is the case where a university researcher uses the patent in order to test whether the invention works the way it is claimed in the patent, which can be considered fair use of the patented invention.[40]

In the Myriad case, most of the third users were clinicians in public or private non-profit hospitals. Even though the intent of this type of institutional users is non-commercial in nature, it remains to be seen whether the use of the patented invention against the payment of a nominal fee will be qualified as commercial or not. So it is doubtful whether the first criterion would be fulfilled.

(2) The nature of the patented work

In order to be exempted under the fair use doctrine and in line with US copyright law, the amount of time, money, and *effort of the inventor/patent holder* should be taken into account on a case-by-case basis.[41] Use of the patent would appear not to be fair use if the protected technology is revolutionary or disruptive, requires millions of dollars (or Euros) for its development, or is owned by small companies or independent inventors. On the other hand, use of patent would appear 'fair' if the patented technology only offers a minimal improvement in a crowded field, if the investment is minimal, or if the patent is held by large companies or universities.[42]

[38] For more on the discussion on legal transplants, see Legrand (1997); Pintens (1998); Watson (2000); Watson (1993); Zweigert and Kötz (1996).

[39] See O'Rourke (2000), at p. 1243.

[40] De Larena (2005), at p. 811.

[41] De Larena (2005), at pp. 811–812.

[42] De Larena (2005), at pp. 811–812.

In the Myriad case, it has been repeatedly argued that the 'discovery' of the BRCA genes was the result of perseverant, yet routine work,[43] as was the establishment of the association between the gene and the disease. In light thereof, the second criterion might well be fulfilled.

(3) The amount and substantiality of the portion used—the nature of the advance of the infringing work—transformative use

The third factor appears to be the most important condition of the fair use test in US copyright law. This factor would focus on the *type* and manner rather than on the pure *volume* of the use by the alleged infringer on a case-by-case basis.[44] It may be argued that an exact use of the invention would constitute an infringement, whereas a transformative use could constitute a 'fair' use of the patented invention.

In the Myriad case, the lab clinicians use the (knowledge about) the patented BRCA genes in their own, 'home brewn' methods.[45] Even though such use is not identical to the work performed by the inventor who isolated and characterised the relevant gene(s), establishing a link between those genes and a disease can probably not be qualified as transformative either. So it remains uncertain whether the third criterion would be fulfilled.

(4) The effect of the use upon the potential market

The fourth and last criterion relates to the effect of the use upon the market. Copyright protection aims at providing (economic) incentives to promote creations. This is even truer for patent law, as (scientific) experiments can be significantly more costly.[46] An infringement would clearly exist if a reasonably priced research licence is easily accessible to all who qualify. Conversely, a fair use of the invention would be accepted when even non-competitors are denied access to a licence, particularly when the technology would not be commercialised by the patentee.[47]

In the Myriad case, this last condition is fulfilled in the most convincing way. There is wide evidence that Myriad was not willing to provide reasonably priced licences. On the other hand, the fact that public and private non-profit hospitals offered in-house tests at nominal cost diminished the potential market share of Myriad for the BRCA tests.

It is often suggested that the fair use test does not require that *all* four factors be present, but rather requires a comprehensive *overall* assessment, where one factor is not prioritised over another. With that in mind, measuring the Myriad case against the four factors of the fair use doctrine leads us to believe that an unambiguous answer to the question whether the four conditions are clearly, indisputably, and

[43] Baldwin (2007); Matthijs (2007).

[44] De Larena (2005), at pp. 811–812.

[45] Matthijs (2007).

[46] De Larena (2005), at p. 813.

[47] De Larena (2005), at p. 813.

overall met in this controversial case is difficult to give. It is not sure at all whether the current behaviour of clinicians would be shielded under a fair use exception. Applying the fair use concept does not allow prediction of the outcome of a dispute in advance, and the 'concept' can therefore not be regarded as a 'standard'. One will not only have to wait for the decision of the court, but it should be borne in mind that the decision pattern of a court may vary over the years. Hence, the fair use test does not simply and (recti)linearly contribute to legal certainty. Conversely, it is by no means certain whether the current restrictive licensing behaviour of Myriad would be considered unlawful, unreasonable, and 'unfair' under the fair use doctrine.

6 Conclusion

Our conceptual analysis of the US fair use exception leads us to conclude that the fair use concept may inspire European legislators in designing institutional and legal responses to monitor the exercise of patent rights in an attempt to safeguard an adequate balance between private and public interests and operationalise the 'social contract' in the post-grant phase.

However, our exploration of the application of the US fair use concept in one contentious real life case, namely the Myriad (breast cancer genes) case, brings us to believe that the introduction of a fair use doctrine in European patent law is not very helpful in remedying restrictive and exorbitant licensing behaviour and preserving the 'social contract' on which patent law is based in the area of genetics. Further research is needed to explore to what extent our limited conclusion holds when testing the US fair use concept in other technological sectors, such as ICT or telecom. At first sight, these sectors seem less prone to restrictive licensing behaviour. Due to the nature of the products, and to the importance of interoperability and compatibility, there is a recurrent need among companies to (cross-)license their patents. However, when dealing with standard essential patents, endless debates on the exact scope and level of FRAND licensing terms arise. The fair use concept might prove to be a valuable instrument in this context.

Future research could also provide a more advanced comparison of the US fair use exception and European functional look-alikes, such as the research exception and the compulsory licence. An investigation of the similarities and differences between the four fair use components in US patent law and the seven research exception parameters in European patent law[48] could shed some new light on the various motivations and approaches in Europe and the US in dealing with

[48] The first of those parameters relates to the *direct* goal of the research: is the research carried out *on* or *with* the patented device? A second parameter focuses on the *indirect* goal of the experiment: is the research performed with a commercial or non-commercial (fundamental) goal in mind? Especially this last criterion highly resembles the first fair use factor (*intent*). The seven parameters were the result of a comparative and in-depth analysis of the research exceptions in Germany, the Netherlands, and Belgium; see Van Overwalle (2000). A somewhat more simplified approach—in terms of parameter analysis—can be found in van Zimmeren and Van Overwalle (2014).

limitations in patent law. A study of the distinction between fair use and compulsory licence may trigger interesting discussions on the conditional/unconditional nature of use by third parties. In case of fair use, unconditional use by third users is allowed, whereas in the regime of compulsory licences, remuneration for the patent holder is often contemplated. The comparison becomes more challenging when one imagines that a fee would be charged for the fair use as well.[49]

Last but not least, future research might go beyond testing to what extent the current fair use factors may be operationalised in European patent law and might field test Strandburg's Patent Fair Use 2.0 Proposal. In case this research leads to the conclusion that the fair use doctrine is not amenable to European patent law, yet other alternatives will have to be contemplated to maintain the equilibrium between exclusive rights and public welfare in cases of unreasonable licensing behaviour.

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References

Baldwin T (2007) Ethics and patents for genetic diagnostic tests. In: Van Overwalle G (ed) Gene patents and public health. Bruylant, Brussel

Bessen J, Meurer M (2008) Patent failure: how judges, bureaucrats and lawyers put innovators at risk. Princeton University Press, New Jersey

Boldrin M, Levine DK (2008) Against intellectual monopoly. Cambridge University Press, Cambridge

Burk DL, Lemley MA (2009) The patent crisis and how the courts can solve it. The University of Chicago Press, Chicago

Caulfield T, Bubela T, Murdoch CJ (2007) Myriad and the mass media: the covering of a gene patent controversy. Genet Med 9:850–855

De Larena LR (2005) What copyright teaches patent law about "Fair Use" and why universities are ignoring the lessons. Oreg Law Rev 84:779

Drahos P (1996) A philosophy of intellectual property. Dartmouth Publishing Group, Aldershot

Gervais D (2003) The TRIPS Agreement. Drafting history and analysis. Sweet & Maxwell, London

Goldstein P (2001) International copyright. Principles, law and practice. Oxford University Press, Oxford

[49] O'Rourke already reflected on *conditional* fair use, where a fee would be demanded; see O'Rourke (2000), at pp. 1234–1235.

Goldstein P, Hugenholtz PB (2010) International copyright. Principles, law and practice. Oxford University Press, Oxford
Guibault LMCR (2002), Copyright limitations and contracts. In: Information law series. Kluwer Law International, The Hague
Hart M (1998) The proposed directive for copyright in the information society: nice rights, shame about the exceptions. Eur Intellect Prop Rev 20:169
Hopkins M et al (2007) DNA patenting: the end of an era? Nat Biotechnol 25:185
Hugenholtz PB, Okediji RL (2008) Conceiving an international instrument on limitations and exceptions to copyright, 06 March 2008
Huys I, Van Overwalle G, Matthijs G (2011) Gene and genetic diagnostic method patent claims. A comparison under current European and US patent law. Eur J Hum Genet (EJHG) 19 (10):1104–1107
Huys I, Matthijs G, Van Overwalle G (2012) The fate and future of patents on human genes and genetic diagnostic methods. Nat Rev Genet 13(6):441–448
Jaffe AB, Lerner J (2004) Innovation and its discontents: how our broken patent system is endangering innovation and progress. Princeton University Press, Princeton
Jensen K, Murray F (2005) Intellectual property landscape of the human genome. Science 310:239
Legrand P (1997) The impossibility of legal transplants. Maastricht J Eur Comp Law 4:111ff
Machlup F (1959) Review of the patent system. Study for the United States Senate, Washington D.C.
Matthijs G (2007) DNA diagnostics in practice. In: Van Overwalle G (ed) Gene patents and public health. Bruylant, Brussel
Matthijs G, Hodgson S (2008) The impact of patenting on DNA diagnostic practice. Clin Med 8:58–60
Matthijs G, Huys I, Van Overwalle G, Stoppa-Lyonnet D (2013) The European breast cancer gene patent oppositions and appeals: coloring in the lines. Nat Biotechnol 31:704–710
O'Rourke MA (2000) Toward a doctrine of fair use in patent law. Columbia Law Rev 100:1117
Penrose ET (1951) The economics of the international patent system. John Hopkins Press, Baltimore
Pintens W (1998) Inleiding tot de rechtsvergelijking. Universitaire Pers, Leuven
Reichman JH, Okediji RL (2012) When copyright law and science collide: empowering digitally integrated research methods on a global scale. Legal studies research paper series. Research Paper No. 13-03, University of Minnesota Law School
Samuelson P (2008–2009) Unbundling fair uses. Fordham Law Rev 2537
Sheehan J, Guellec D, Martinez C (2003) Business patenting and licensing: results from the OECD/BIAC survey. In: Patents, innovation and economic performance, proceedings of the OECD conference on IPR, Innovation and economic performance, 28 August 2003
Sterckx S (2005) The ethics of patenting – uneasy justifications. In: Drahos P (ed) Death of patents. Lawtext Publishing, Oxon, pp 175–211
Strandburg KJ (2011) Patent fair use 2.0. Univ Calif (UC) Irvine Law Rev 265
Strowel A (1993) Droit d'auteur et copyright – Divergences et convergences. Bruylant, Brussels
Van Overwalle G (2000) Klinische proeven en volksgezondheid. Naar een herijking van het algemeen belang in het octrooirecht [Clincial trials and public health. Reassessing the notion of public interest in patent law]. Tijdschrift voor Privaatrecht (TPR) [J Priv Law] 899–968. http://ssrn.com/abstract=1718619
Van Overwalle G (2007) Gene patents and public health. Setting the scene. In: Van Overwalle G (ed) Gene patents and public health. Bruylant, Brussel, pp 11–24
Van Overwalle G, van Zimmeren E (2009) Functions and limits of patent law. In: Claes E, Devroe W, Keirsbilck B (eds) Facing the limits of the law. Springer, Heidelberg, pp 415–442
van Zimmeren E (2011) Towards a new patent paradigm in the biomedical sector? Facilitating access, open innovation and social responsibility in patent law in the US, Europe and Japan. PhD Thesis, University of Leuven, 16 May 2011
van Zimmeren E, Van Overwalle G (2011) A paper tiger? Compulsory license regimes for public health in Europe. Int Rev Intellect Prop Competition Law (IIC) 42:4–40

van Zimmeren E, Van Overwalle G (2014) A false sense of security offered by zero-price liability rules? Research exceptions in the US, Europe and Japan in an open innovation context. In: Okediji R, Bagley M (eds) Global perspectives on patent law. Oxford, Oxford University Press, 379–417
Watson A (1993) Legal transplants. Edinburgh, 1974 – Athens
Watson A (2000) Legal transplants and European private law (Ius Commune Lectures on European Private Law). Electronic J Comp Law 4.4. http://www.ejcl.org/ejcl/44/44-2.html. Last visited 18 June 2013
World Intellectual Property Indicators (2011) WIPO economics & statistics series. World Intellectual Property Organization, Geneva
Zweigert K, Kötz H (1996) Einführung in die Rechtsvergleichung auf dem Gebiete des Privatrechts. Mohr, Tübingen